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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/626,166	07/23/2003	Gregory Everett Amidon	PC28053	9717
23913	7590	10/23/2007		
PFIZER INC Steve T. Zelson 150 EAST 42ND STREET 5TH FLOOR - STOP 49 NEW YORK, NY 10017-5612			EXAMINER ROGERS, JAMES WILLIAM	
			ART UNIT 1618	PAPER NUMBER
			MAIL DATE 10/23/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/626,166	Applicant(s) AMIDON ET AL.	
	Examiner James W. Rogers, Ph.D.	Art Unit 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 September 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicants amendments to the claims filed 09/28/2007 have been entered, applicants have amended claim 23. Currently claims 1-26 are pending. Any rejection from the previous office action filed 09/14/2006 not addressed in the office action below has been withdrawn.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-4,8-9,13-20 and 24-26 are rejected under 35 U.S.C. 102(e) as being anticipated by Holman (US 6,277,875 B1, cited by applicants), for the reasons set forth in the previous office action filed 09/14/2006.

Response to Arguments

Applicant's arguments filed 09/28/2007 have been fully considered but they are not persuasive.

Applicants assert that their formulation is sustained release while the formulations of Holman are immediate release; therefore applicants surmise Holman cannot anticipate their claimed invention. Applicants further assert that Holman fails to disclose the inclusion of a starch having the claimed tensile strength. Applicants then

point to their own disclosure as evidence that pre-gelatinized starch will not have the same tensile strength and will vary from lot to lot, even from the same manufacturer.

In response to applicants' assertions, firstly "sustained release" appears in the preamble of applicants' claims and is essentially an intended use for the composition, ("where a patentee defines a structurally complete invention in the claim body and uses the preamble only to state a purpose or intended use for the invention, the preamble is not a claim limitation"); *Kropa v. Robie*, 187 F.2d at 152, 88 USPQ2d at 480-81. Besides the above, applicants have not pointed to the section within Homan and the examiner could not find a passage within Homan that stated the dosage forms were all immediate release. The formulations of Holman were said to be preferably in an oral dosage form such as tablets, the dosage form contains all of applicant's claimed ingredients. Since the formulation of Holman is the same as applicant's claimed invention, Holman anticipates applicants' invention. The argument from applicants that Holman is silent on the tensile strength of the pre-gelatinized starch is also found non-persuasive.

Applicants have not shown that the pre-gelatinized starch within Holman would not have the claimed tensile strength. Instead, applicants point to their disclosure that shows the tensile strength can vary from various batches of commercially available starches.

However, applicants have not disclosed at least within their claims what feature of the starch would lead to the claimed tensile strength, such as the ratio of amylase/amylopectin or the molecular weights of the two carbohydrate glucoses. Since the only feature that must be present in their claims is pre-gelatinized starch, any reference with the claimed ingredients in a tablet form will anticipate applicants' claims. It

appears as though applicants are attempting to claim a new and/or undiscovered property of an old composition. Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case of either anticipation or obviousness has been established. Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. In re Best, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977).

Claims 1-4, 8-14, 19-20, 22, 24 and 26 are rejected under 35 U.S.C. 102(e) as being anticipated by Patel et al. (US 2003/0180352), for the reasons set forth in the previous office action filed 09/14/2006.

Applicant's arguments filed 09/28/2007 have been fully considered but they are not persuasive.

Applicants assert that Patel merely provides a laundry list of active ingredients and excipients that can be included in various types of dosage forms but there is not specific teaching within Patel of a sustained-release pramipexole composition dispersed in a matrix comprising a hydrophilic polymer and a starch. Applicants also disclose as above that Patel does not mention the tensile strength of the starch.

The relevance of these assertions is unclear. While the disclosure of Patel broadly disclosing numerous actives and excipients, it actually shows that pharmaceutical compositions are well known to contain numerous types of actives and excipients. Patel essentially shows that numerous ingredients were well known at the

time of applicant's invention to be used in pharmaceutical formulations including sustained release tablet forms. The remarks above for Holman are incorporated herein for the tensile strength of the starch.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made

Claims 1-22 and 24-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Holman (US 6,277,875 B1, cited by applicants), for the reasons set forth in the previous office action filed 09/14/2006.

Claims 1-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Patel et al. (US 2003/0180352), for the reasons set forth in the previous office action filed 09/14/2006.

Applicant's arguments filed 09/28/2007 have been fully considered but they are not persuasive.

Applicants assert that as in their arguments described above neither Holman nor Patel disclose the tensile strength of the starch and the examiner provided no motivation for either reference to use a starch with the required tensile strength.

The remarks above by the examiner for why Holman and Patel meet the tensile strength are incorporated herein. Regarding applicants assertion that there is no motivation to use the tensile strength as claimed, as stated above the examiner takes this strength to be an inherent property of any pre-gelatinized starch absent any physical limitations that would preclude certain starches, such as the ratio of amylase/ amylopectin or the molecular weights of the two carbohydrate glucoses. It appears as though applicants are attempting to claim a new and/or undiscovered property of an old composition. Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case of either anticipation or obviousness has been established. Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. In re Best, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977).

Claims 1-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Holman (US 6,277,875 B1, cited by applicants) in view of Khan et al. (US 5,656,296, cited by applicant) in view of Petrus et al. (WO 00/59477 A1, cited by applicants) in further view of Michaud et al. (EP 0,933,079 A1, cited by applicants), for the reasons set forth in the previous office action filed 09/14/2006.

Applicants assert that Michaud is directed to tablets that are rapid disintegration which is in contrast to applicants claimed sustained-release composition. Applicants then asserts that Michaud does not disclose the use of a starch having the claimed tensile strength rather the entire tablet (not the starch alone) have the disclosed tensile

strength. Thus applicants conclude that one having ordinary skill in the art would not apply the rapidly disintegrating tablets with the immediate release composition of Homan to arrive at the claimed sustained-release composition of the present invention.

The relevance of these assertions is unclear. The remark above for why Holman discloses the same composition as applicant's claims is incorporated herein. Regarding applicants assertions on Michaud, firstly Michaud was used only to show that compressed formulations comprising pre-gelatinized starch within applicants claimed tensile strength range was already known in the art at the time of applicant's invention. Secondly from the disclosure of Michaud the compressed tablets contained nearly all starch (98.8% in table 3, 99.25% in table 6, 99.25% in table 9). The very small amount of other ingredients would obviously not change the total tensile strength of the tablet since they are used in such a small amount. Besides the argument above since Holman and Michaud disclose pre-gelatinized starch as in the remarks above applicant's claims are not patentable over the combined teachings of the art above.

Conclusion

No claims are allowed at this time.

Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James W. Rogers, Ph.D. whose telephone number is (571) 272-7838. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Hartley can be reached on (571) 271-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


MICHAEL G. HARTLEY
SUPERVISORY PATENT EXAMINER